## REMARKS

Applicants have carefully reviewed the Office Action mailed September 20, 2006, and thank Examiner Rogers for the detailed review of the pending claims. Claims 1, 5 – 17, and 21 – 37 are pending. In this response, Claims 1, 17, 23, 27 and 36 have been amended, Claim 34 has been cancelled without prejudice, and new claims 38 - 44 have been added. Support for the new claims is found in the specification and the drawings, and no new matter has been added. For at least the reasons set forth below, Applicants respectfully traverse the foregoing rejections. Further, Applicants believe that there are reasons other than those set forth below why the pending claims are patentable, and reserve the right to set forth those reasons, and to argue for the patentability of claims not explicitly addressed herein, in future papers. Applicants respectfully request reconsideration of the present application in view of the above amendments and the following remarks.

### Claim Rejections Under 35 U.S.C. § 112

The Examiner rejected Claims 1, 17, 23, 27, 34, and 36 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement because, per the Office Action, the Examiner could find no support in the specification for the limitation that the injection of purified alginate liquid and injection of the calcium chloride solution can be at variable rates, either within an injection stage or across injection stages. The rejection is respectfully traversed. As one example of support for the limitation, Applicants direct the Examiner to Par. 64, page 12, of the specification. Because the limitation is supported by at least the indicated language, Applicants request that the rejection be withdrawn and the claims allowed.

The Examiner also rejected claims 34 and 36 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement because, per the Office Action, while the specification has support for an alginate with a molecular weight range of 65,000 g/mol to

200,000 g/mol, it does not have support for the broader limitation in which the alginate can be any molecular weight below 250,000. The rejection is respectfully traversed. Claim 34 is cancelled without prejudice, and Claim 36 is amended herein to state a molecular weight range between about 65,000 and about 200,000. Applicants therefore request that the rejection be withdrawn and the claims allowed as amended.

The Examiner also rejected claims 1, 17, 23, and 27 under 35 U.S.C. §112, second paragraph, because according to the Office Action, the phrase "can be" rendered the claims indefinite. The rejection is respectfully traversed. Claims 1, 17, 23, and 27 are amended herein to remove the rejected language and to state "are". Applicants request that the rejection be withdrawn in light of this amendment.

**Claim Rejections Under 35 USC § 102**

The Examiner rejected claims 1, 5-17, 21-22, 35 and 37 under 35 U.S.C. §102(b) as being anticipated by U.S. Publication No. 2001/0031978 A1 ("Kipke"). The rejection is respectfully traversed.

To anticipate a claim, the reference must teach every element of the claim. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Kipke fails to meet the standard for anticipation. The Office Action cites Kipke for the proposition that Kipke teaches a method for forming an endovascular occlusion comprising of controlling the injection rate and pressure of a purified alginate liquid and a calcium chloride solution into a vascular site. However, as discussed herein, Kipke does not anticipate because it does not teach all elements of the present invention, particularly as represented by independent Claims 1 and 17 as amended.

Independent Claim 1 and other claims have been amended to further clarify the distinction of embodiments of the present invention from Kipke. As one example, independent Claim 1 as amended claims:

> A method for forming an endovascular occlusion comprising the step of controlling injection of a purified alginate liquid and injection of a calcium chloride solution to a targeted area within a vascular system, wherein injection of the purified alginate liquid and injection of the calcium chloride solution begin or end asynchronously are at variable injection rates, either within an injection stage or across injection stages. [Emphasis added]

Thus, as set out in Claim 1, without limiting the scope of the invention, the present invention comprises the novel element "wherein injection of the purified alginate liquid and injection of the calcium chloride solution are at variable injection rates, either within an injection stage or across injection stages."

In contrast, the cited reference, Kipke, does not teach or disclose injection wherein injection of the purified alginate liquid and injection of the calcium chloride solution are at variable injection rates, either within an injection stage or across injection stages. Kipke does not teach or disclose any form of staged injection where the injection of the purified alginate liquid and injection of the calcium chloride solution do not occur at the same rate, or where they occur at rates that are variable with respect to the other. Furthermore, Kipke speaks only in terms of predetermined injection rate or rates and precise control of injection rate. This terminology does not cover variable rates during injection, which would imply a non-precise, non-predetermined, or variable rate injection. In contrast, Claim 1 as amended includes the explicit limitation that the injections "...are at variable injection rates, either within an injection stage or across injection stages." Thus, Kipke fails to anticipate independent Claim 1, and similarly, independent Claim 17, and those claims and their respective dependent claims should therefore be allowed as amended.

In addition, Claims 35 and 37, each depending from Claim 1, have the added limitation of a concentration of less than 25 cP. Applicants respectfully disagree with the assertion in the

Office Action that, at Figure 7a, Kipke discloses a concentration at or a little lower than 25 cp from the graph. In that regard, Applicants respectfully direct the Examiner to the corresponding Figure 7a in the related issued patent, U.S. Patent 6,592,566, where the Figure more clearly shows this distinction from the present claim. Because Kipke does not disclose this added limitation, it does not anticipate at least Claims 35 and 37, and the rejection should be withdrawn.

For at least these reasons, Applicants request that the rejection be withdrawn and that Claims 1, 5-17, 21-22, 35 and 37 be allowed as amended.

**Claim Rejections Under 35 USC § 103**

The Examiner rejected claims 1, 5-17, 21-22, and 34-37 under 35 U.S.C. §103(a) as being unpatentable over Kipke. The rejection is respectfully traversed.

It is well known that "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. *Accord* M.P.E.P. § 706.02(j). Moreover, the mere fact that references can be combined or modified does not render the resulting combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F2d 680, 16 U.S.P.Q 2d 1430 (Fed. Cir. 1990).

MPEP Section 2143 sets forth the basic requirements for the Patent and Trademark Office to establish *prima facie* obviousness as follows: "To establish a *prima facie* case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."

The case law "makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for showing of the teaching or motivation to combine prior art references." *In re Dembiczak,* 175 F.3d 994,

999 (Fed. Cir. 1999); see *also Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 665 (Fed.Cir. 2000) This is because "[c]ombining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability—the essence of hindsight." *Dembiczak,* 175 F.3d at 999. Thus, it is established law that one "cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *Ecolochem, Inc. v. Southern Cal. Edison Co.*, 227 F.3d 1361, 1371, 56 USPQ2d 1065 (Fed. Cir. 2000) (citing *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1780, 1783 (Fed. Cir. 1988)).

Therefore, the courts have consistently held that a person of ordinary skill in the art must not only have had some motivation to combine the prior art teachings, but some motivation to combine the prior art teachings in the particular manner claimed. *See, e.g., In re Kotzab,* 217 F.3d 1365, 1371 (Fed.Cir. 2000) ("Particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination *in the manner claimed.*" (emphasis added)); *In re Rouffet*, 149 F3d 1350, 1357 (Fed.Cir. 1998) ("In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor, and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination *in the manner claimed.*" (Emphasis added)).

Regarding Claims 33-34 and 36, the Office Action acknowledges that Kipke is silent as to the molecular weights of its alginates. However, the Office Action asserts that "…the Kipke application obviously incorporates the same alginates with the same MW because both applications bought from the same source (Provera) and apparently used the same commercially available alginates…" Based on this assumption, the Office Action purports to "[shift] the burden…to the applicants to show that the molecular weight range claimed in their currently claimed invention is not encompassed within the Kipke application."

At this time, Applicants continue to search for information concerning the nature of Pronova alginate material referred to in Kipke. Kipke claims priority back to February 2000 and was filed in February 5, 2001, while most Applicants were employed in Arizona at Arizona State

University. After that filing and before the present filing, Applicants moved to the University of Michigan in Ann Arbor, Michigan, thus complicating the search for information. Applicants respectfully reserve the right to amend, supplement, or further respond when and if additional information becomes available.

Regardless, Applicants respectfully assert that the present assumption about the source of alginates is faulty and that the Office Action fails to support a *prima facie* case of obviousness with a shift of burden back to the Applicants. As the Office Action admits, Kipke is completely silent as to molecular weight of any alginate used therein; in fact, the term "molecular weight," or any abbreviation thereof, does not appear anywhere in Kipke. A source of alginate is identified in Kipke as "Pronova" (see e.g., Paragraphs 45, 55, and 56); however, Pronova is disclosed only in conjunction with the purification of alginate (e.g., Par. 65 of Kipke, describing the removal of "impurities"), and not in any way connected with the effect of alginate molecular weight, or differences in molecular weight, on the methods disclosed in Kipke.

By comparison, the present application discloses significant investigation of the effects of molecular weight, and differences in molecular weight, on factors like strength, stability, polymer yield, and fatigue resistance. See e.g., Example 2, Paragraphs 83-85; Paragraphs. 98-100; and Figures 8a, 8b, and 12. None these factors is disclosed or taught in the context of molecular weight by Kipke. Simply put, there is no disclosure in Kipke of the molecular weight limitation of the present claims, and there is no basis, except in improper hindsight, to attempt to read such as basis on a potent source of alginate material only. For at least these reasons, Kipke fails to disclose the "all the claim limitations" (MPEP 2143), including the molecular weight limitation, of present Claims 33-34 and 36. The rejection should therefore be withdrawn, and thee claims should be allowed as amended.

The Office Action asserts regarding the limitations on the injection rates of the calcium and alginate solutions in Claims 1 and 5 – 14 that it would have been obvious at the time of the invention to vary the injection rates of the alginate and calcium chloride solution because Kipke discloses that the calcium alginate is optimized for forming an endovascular occlusion by controlling the injection rate, pressure and viscosity of the purified alginate solution and calcium

chloride solution. The rejection is respectfully traversed. For at least the reasons set out in the discussion with respect to Section 102 above and incorporated here, Kipke does not teach or disclose injection into a vascular system where the purified alginate liquid and calcium chloride injections are at variable injection rates, either within an injection stage or across injection stages, as required by independent Claims 1 and 17 and their respective dependent claims. Because this claim element is missing, Kipke cannot support an obviousness rejection under Section 103(a), and the rejection should be withdrawn and the claims should be allowed.

The Office Action also rejected Claims 1, 5 - 17, and 21 – 37 under 35 U.S.C. 103(a) as being unpatentable over the combination of Kipke in view of Reeves in view of Ji. The rejection is respectfully traversed.

The Office Action acknowledges that Kipke does not disclose injecting the calcium chloride into a balloon nor does the application disclose the use of a coil in conjunction with the purified alginate and calcium chloride solution. Moreover, with respect to Claims 25 and 26, Kipke additionally does not teach or disclose at least the element of providing an ion-permeable balloon to a targeted area in a vascular system and injecting calcium chloride solution into the balloon.

The deficits of Kipke are not cured by combination with Reeves. Reeves discloses only a vascular balloon system wherein an uninflated balloon is inserted into vasculature on the end of a stylet, the stylet is withdrawn, and the balloon is inflated with premixed materials delivered into the interior balloon through a passageway of a single delivery catheter, with the catheter withdrawn after inflation. (See e.g., Col. 6, lines 10, 23, 40 – 52) However, unlike the present application, Reeves does not teach or disclose any method or system for the delivery and formation of a multi-component polymer, like the calcium alginate polymer of the present invention.

The deficits of Kipke and Reeves are not cured by combination with Ji. At best, Ji discloses only an endovascular embolic composition formed as a "so-called ointment…in semisolid-semiliquid form." (Col. 4, lines 44-45). Unlike the present invention, the "ointment" of Ji is formed only outside the target animal (e.g., Col. 7, lines 53 – Col. 8, line 3) and only then

is it injected into a target area in the host. Thus, unlike the present invention, Ji does not teach or disclose a polymer formed *in vivo* from a plurality of components, nor does it, by itself or in combination with Kipke and/or Reeves, teach or disclose the creation, formation, or use of such a component *in vivo* in conjunction with any assist device. Because all of these elements are lacking, the attempted combination of Kipke, Reeves, and Ji fails to support a *prima facie* case of obviousness; any attempt to combine same is hindsight that improperly uses the present invention as a blueprint to arrive at a conclusion of obviousness. For at least these reasons, the rejection should be withdrawn, and that claims should be allowed.

## CONCLUSION

In view of the above, the pending claims are believed to be in condition for allowance. Accordingly, reconsideration and allowance are respectfully requested and the Examiner is respectfully requested to pass this application to issue.

Any fees associated with the filing of this paper have already been identified in the transmittals accompanying this paper. However, if any additional fees are required in connection with the filing of this paper that are not identified in any accompanying transmittals, permission is given to charge Deposit Account 18-0013, under order number 65306-0092 in the name of Rader, Fishman and Grauer PLLC.

If the Examiner has any questions or comments, the Examiner is kindly urged to call the undersigned to facilitate prosecution.

Date: March 20, 2007

Respectfully submitted,

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